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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

GUID.027US01

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on February 21, 2006

Signature Tracey M. Dotter

Typed or printed name Tracey M. Dotter

Application Number

101774,051

Filed

2/6/04

First Named Inventor

Bruce Wilson

Art Unit

37167

Examiner

Sirmone, K.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

applicant/inventor.

assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

attorney or agent of record.
Registration number 38,491

attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Mark A. Hollingsworth

Signature

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952-854-2700

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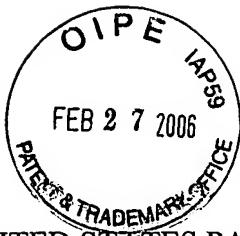
February 21, 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

*Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



SERIAL NO. 10/774,051

PATENT APPLICATION

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: WILSON Examiner: Sirmons, K.
Serial No.: 10/774,051 Group Art Unit: 3767
Filed: 02/06/2004 Docket No.: GUID.027US01
(03-501)
Title: METHOD AND APPARATUS FOR GUIDE CATHETER POSITIONING

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this communication is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on February 21, 2006.

By: Tracey M. Dotter
Tracey M. Dotter

**APPELLANT'S STATEMENT IN SUPPORT OF
PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This statement is presented by Appellant in compliance with the USPTO OG Notice of 12 July 2005 on New Pre-Appeal Brief Conference Pilot Program. Appellant is requesting a pre-appeal brief conference on the belief that the rejections of record are clearly not proper and are without basis. Appellant's request is based upon a clear legal or factual deficiency in the rejections, rather than an interpretation of the claims or the prior art teachings. As such, Appellant believes this request for pre-appeal brief review is appropriate.

Claims 1-8 and 18-20 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,757,827 to *Buchbinder et al.* (hereinafter “*Buchbinder*”). Claims 9 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

The rejection of claims 1-8 and 18-20 under 35 U.S.C. § 102(b) as being anticipated by *Buchbinder* is the only issue on appeal. The central issue on appeal concerns whether each and every element of Appellant's claims 1-8 and 18-20 is found expressly or inherently in *Buchbinder*.

Appellant's rejected claim 1 recites a guiding catheter system comprising, among other features, a handle assembly movably coupled to a flexible shaft, wherein the flexible shaft is

selectably movable between a plurality of discrete positions of a first degree-of-freedom defined relative to the flexible shaft. Appellant's rejected claim 1 further recites that the flexible shaft is restrained in the first degree-of-freedom at each position of the plurality of discrete positions, and that the flexible shaft is movable through a predetermined displacement of a second degree-of-freedom defined relative to the flexible shaft at each position of the plurality of discrete positions.

Appellant's rejected claim 18 recites a catheter assembly comprising means for selectably moving the shaft between a plurality of discrete positions of a first degree-of-freedom defined relative to the flexible shaft, means for restraining a motion of the shaft in the first degree-of-freedom at each position of the plurality of discrete positions, and means for moving the flexible shaft through a second degree-of-freedom defined relative to the flexible shaft at each position of the plurality of discrete positions.

Appellant refers to representative Figures 4-7 of Appellant's disclosure that facilitate a clear understanding of the claim language pertaining to a "plurality of discrete positions" of a first degree-of-freedom defined relative to the flexible shaft.

In contrast to Applicant's claimed structure, the *Buchbinder* apparatus employs threads 66, 67 of deflection member 65 to provide continuous axial displacement of a deflection wire 64. When tip deflection knob 62 is rotated, deflection member 65 is caused to move in an axial direction, that is, either proximally or distally, and deflection wire 64 move similarly in axial motion relative to tubing 63. *Buchbinder* further teaches that axial motion of tip deflection knob 62 is restrained by annular projection 68.

Buchbinder clearly fails to teach a flexible shaft that is selectably movable between a plurality of discrete positions of a first degree-of-freedom defined relative to the flexible shaft. The *Buchbinder* apparatus cannot provide such movement because axial motion of its tip deflection knob 62 is restrained by annular projection 68, which represents a single non-selectable position, and the threads 66, 67 of deflection member 65 provide only continuous axial displacement of a deflection wire 64.

The Examiner appears to acknowledge the continuous axial displacement feature of *Buchbinder* in the final Office Action by stating that "[f]or the record, the device of Buchbinder

is fully capable of an infinite amount of degree of freedom.” Page 4 of the final Office Action, *emphasis added*.

Applicant, as described in paragraph 26 of Applicant’s specification, teaches that “[i]t will be appreciated that the physician can longitudinally and rotationally move the shaft 102 without the use of the handle 124. The handle 124, however, provides a restraint on this motion, thereby allowing such movements to be systematic and controllable.” *Emphasis added*.

The manner in which this “restraint” on shaft motion is implemented is clearly recited in Applicant’s claims 1 and 18. Claim 1 recites a flexible shaft that is selectively movable between a plurality of discrete positions of a first degree-of-freedom defined relative to the flexible shaft. Claim 18 recites means for restraining a motion of the shaft in the first degree-of-freedom at each position of the plurality of discrete positions.

The term “discrete” is understood to mean individually separate and distinct, as is defined, for example, in The New Oxford American Dictionary, Oxford University Press, Inc. (2001), p. 488. Applicant’s recitation of “discrete” positions in the claims is clearly not met by an apparatus that allows for “an infinite amount of degree of freedom.” The Examiner’s characterization of the *Buchbinder* apparatus is factually in error and effectively ignores an important feature of Applicant’s claims.

Appellant’s claims 1 and 18 also recite a flexible shaft having a distal end shaped for accessing a target vessel. *Buchbinder* discloses a steerable guidewire that includes tubing (2, 21, 41, 63) and a deflection wire (3, 23, 42, 64) arranged axially therein. The distal end of the tubing is shaped for reception within a spring coil (7, 22, 45). The deflection wire is tapered and ground to a sharp point (14). The distal point of the deflection wire terminates at a cap or tip (9, 31, 48).

Buchbinder fails to teach, expressly or inherently, a flexible shaft having a distal end shaped for accessing a target vessel. The distal end of the tubing (2, 21, 41, 63) in *Buchbinder* is shaped for reception within a spring coil (7, 22, 45), not for accessing a target vessel. The sharp point of the deflection wire terminates at a cap of the spring coil, and is clearly unsuitable for accessing a target vessel, as the sharp point may undesirably puncture such a vessel. The spring coil is not described as being shaped, and clearly is not described as being shaped for accessing a target vessel.

Because *Buchbinder* does not teach, expressly or inherently, all of the claim limitations of independent claims 1 and 18, these claims are clearly not anticipated by *Buchbinder*.

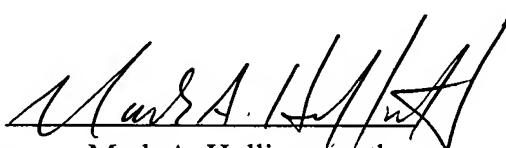
Rejected dependent claims 2-8 and 19-20 are also not anticipated by *Buchbinder*, as these claims depend from base claims that are patentably distinct, and include additional distinguishing features as is discussed in Appellant's responses to the first and final Office Actions.

Appellant believes that this statement, when viewed together with the prosecution history, sets forth clear grounds for a finding that the rejections of record are clearly not proper and are without basis.

The undersigned is of record and with authority to prosecute the appeal on behalf of the Assignee.

Respectfully submitted,

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